

RESPONSE TO AMENDMENT

The amendment filed 10-18-2011 has been entered into the record. Claims 10, 24 and 26 have been cancelled. Claims 1-9, 11-23, 25 and 27 are pending. Claims 1, 3-8, 11-13 and 14-23 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 2, 9, 25 and 27 drawn to an invention nonelected with traverse in the reply filed on 2-11-2011. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Objection/Rejections Withdrawn

The objection to the claims as depending upon non-elected subject matter is withdrawn based on the amendment to the claims.

Rejections Maintained

Claim 1, 3-8, 11-13 and 14-18 and 20-23 are directed to an invention not patentably distinct from the W135 conjugate product claims of commonly assigned 12/351,281; 12/321,464 and 12/321,420 is maintained for reasons made of record.

Applicants indicate that they wish the rejections to be held in abeyance. However, Applicants are reminded that:

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 12/351,281; 12/321,464 and 12/321,420, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if

the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 12/351,281 is maintained for reasons made of record.

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-44 of copending Application No. 12/321,464 is maintained for reasons made of record.

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34 and 67 of copending Application No. 12/321,420 is maintained for reasons made of record.

Claims 1, 3-8, 11-18 and 20-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 03/007985 published 30 January 2003 for reasons made of record in the Office Action mailed 4-21-2011.

WO 03/007985 teaches the conjugation of *N. meningitidis* serotype W135 capsular polysaccharide to CRM197 (see pages 16-17). The W135 purification and conjugation resulted in oligosaccharides with an average degree of polymerization of about 15 to 20. The isolation and conjugation procedures are identical to that which was employed in the instant specification and the specification teaches that the W135 capsular polysaccharides were purified and conjugated as identically described in WO 03/007985 (see pages 24-26 of the instant specification). WO 03/007985 teaches the conjugate of W135 with CRM197 can be combined with other conjugates (see page 22). The conjugates may be provided in lyophilized or liquid forms (see page 8). WO 03/007985 teaches the conjugates may be combined with other non-meningococcal or non-neisserial antigens and preferred to include proteins from serogroup B of *N. meningitidis* (see page 6, line 10- page 7, line 30). Antigens from pneumococcus, hepatitis A virus, hepatitis B virus, *B. pertussis*, diphtheria, tetanus, *H. pylori*, polio and/or *H. influenzae* are particularly preferred.

Applicant's arguments have been considered but are still not persuasive. It is Applicants burden to establish that the product of the prior art is different than the instantly claimed product. As the instantly claimed conjugates are made by the identical process as the prior art, the compositions of the prior art necessarily have the recited structures present and uses the same strain W135 5554 see bactericidal antibody data at pages 20 and 27 where all the immunogens generate antibodies that are reactive and bactericidal against the 5554. The skilled artisan would necessarily recognize that the conjugated polysaccharide immunogen is from the W135 5554 strain. As such, the property is necessarily present as the conjugated polysaccharide is made by the same process and therefore necessarily has the recited properties. Applicants argue that one

skilled in the art could modify acetylation at any point, however the method employed in the instant specification to conjugate the W135 polysaccharide does not deviate from that of the WO 03/007985 document so it is unclear as to how the method of the prior art deviates from that of the instant specification. This is also not persuasive as the process described in the art uses polysaccharide derived from the same strain and utilizes the same process of the instant specification. Applicants own specification admits and teaches that it specifically used the conjugation method of the WO 03/007985 document. Therefore, the product produced by the prior art is the same that is described in the specification as having particular acetylation amounts as the same starting material was used and the same conjugation method was employed. The percent acetylation and structure is inherent to the conjugated polysaccharide.

Since the Office does not have the facilities for examining and comparing applicant's conjugated polysaccharide with the conjugated polysaccharide of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 1, 3-8, 11-18 and 20-23 stand rejected under 35 U.S.C. 102(e) as being anticipated by Constantino (US 2009/0117148, with priority to June 20, 2002) or Constantino US 2009/0182129, with priority to June 20, 2002) or Constantino (US 2009/0130147, with priority to June 20, 2002) or Constantino (US 2005/0106181, with priority to June 20, 2002) for reasons made of record in the Office Action mailed 4-21-2011.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference

was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants argue that all of the Constantino references are divisionals or continuations of the national stage filing of WO 03/007985 and as such, these rejections should fall on the same basis. This is not persuasive as the rejection over WO 03/007985 does not fail and as such, the rejections over the Constantino references are maintained for reasons made of record.

Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/007985 published 30 January 2003 in view of WO 03/080678, published October 2, 2003, filed March 23, 2003) for reasons made of record in the Office Action mailed 4-21-2011.

Applicant's arguments have been carefully considered but are not persuasive. Applicants argue that since the WO 03/007985 document fails the combination over the reference fails. It is noted that the rejection over WO 03/007985 does not fail for reasons set forth of record.

Status of Claims

Claims 1, 3-8, 11-23 stand rejected. All other claims are withdrawn from consideration or are cancelled.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Gary Nickol can be reached at 571-272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner